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9
10 **IN THE UNITED STATES DISTRICT COURT**
11 **FOR THE WESTERN DISTRICT OF WASHINGTON**
12

13 STATE OF WASHINGTON,

14 Plaintiff,

15 v.

16 UNITED STATES DEPARTMENT OF
17 HEALTH AND HUMAN SERVICES;
18 ALEX M. AZAR, in his official capacity as
the Secretary of the United States
19 Department of Health and Human Services,

20 Defendants.
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Case No. 2:20-cv-01105-JLR

**DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFF'S
MOTION FOR PRELIMINARY
INJUNCTION**

Hearing: August 14, 2020

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INTRODUCTION

On June 19, 2020, the Department of Health and Human Services (HHS) published a rule designed to enforce nondiscrimination provisions in healthcare and to remove regulatory burdens (the “2020 Rule,” “Final Rule,” or “Rule”). The Rule hews closely to the underlying text of Section 1557 of the Affordable Care Act (“ACA”), which incorporates protections from other statutes. In 2016, a prior iteration of the Rule (the “2016 Rule”) had attempted to impose a number of requirements not compelled by the ACA. A district court partially vacated the 2016 Rule—including eliminating “gender identity” from its definition of “on the basis of sex”—after determining that HHS had exceeded its authority in issuing the 2016 Rule.

Plaintiff, the State of Washington, seeks a preliminary injunction against three aspects of the 2020 Rule, arguing in part that HHS should have retained provisions vacated from the 2016 Rule. Plaintiff cannot show how it has standing to challenge the 2020 Rule. Moreover, even if plaintiff could show standing, plaintiff fails to demonstrate a likelihood of success on the merits: HHS’s decision to rely on the underlying text of Title IX rather than define “on the basis of sex” was legally permissible and justified by reasoned decisionmaking; the 2020 Rule’s religious exemption was mandated by law; and HHS properly determined what constitutes a “covered entity.” Plaintiff has thus failed to satisfy the exceedingly high threshold for enjoining agency action. And even if plaintiff could, there is no indication that the harm it alleges is *irreparable*. Plaintiff’s request for a preliminary injunction should be denied.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

This case arises from HHS’s efforts to implement Section 1557 of the Affordable Care Act. Section 1557 applies long-standing anti-discrimination principles to health programs or activities by incorporating four federal anti-discrimination laws into the ACA. Specifically, Section 1557 directs that

[e]xcept as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil

1 Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education
 2 Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of
 3 1975 (42 U.S.C. 6101 et seq.), or section [504 of the Rehabilitation Act of 1973
 4 (29 U.S.C. 794)], be excluded from participation in, be denied the benefits of, or
 5 be subjected to discrimination under, any health program or activity, any part of
 6 which is receiving Federal financial assistance, including credits, subsidies, or
 7 contracts of insurance, or under any program or activity that is administered by an
 Executive Agency or any entity established under [Title I of the ACA] (or
 amendments). The enforcement mechanisms provided for and available under
 such title VI, title IX, section [504], or such Age Discrimination Act shall apply
 for purposes of violations of this subsection.

8 42 U.S.C. § 18116(a). Section 1557 states that the Secretary of HHS “may” (but not that he
 9 must) issue implementing regulations. § 18116(c). As relevant here, Title IX in turn provides that
 10 “[n]o person . . . shall, on the basis of sex, be excluded from participation in, be denied the
 11 benefits of, or be subjected to discrimination under any education program or activity receiving
 12 Federal financial assistance.” 20 U.S.C. § 1681(a). Title IX states that it does not apply to
 13 religious organizations where it would conflict with the religious tenets of such organizations,
 14 § 1681(a)(3), and that nothing in it “shall be construed to require or prohibit any person, or
 15 public or private entity, to provide or pay for any benefit or service, including the use of
 16 facilities, related to an abortion,” *id.* § 1688.

17 **A. HHS’s 2016 Rule**

18 Acting under its statutory authority to “promulgate regulations to implement” Section
 19 1557, 42 U.S.C. § 18116(c), HHS issued a rule in May 2016, codified at 45 C.F.R. Part 92 (“the
 20 2016 Rule”). *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375
 21 (May 18, 2016). As relevant here:

22 i. The 2016 Rule prohibited discrimination on the basis of sex, and explicitly
 23 defined “[o]n the basis of sex” to include “discrimination on the basis of pregnancy, false
 24 pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical
 25 conditions, sex stereotyping, and gender identity.” *Id.* at 31,467. The 2016 Rule further defined
 26 “[g]ender identity” to include “an individual’s internal sense of gender, which may be male,
 27 female, neither, or a combination of male and female....” *Id.* The 2016 Rule listed several
 28

specific examples of prohibited discrimination. *See, e.g., id.* at 31,471 (codified at 45 C.F.R. § 92.207). HHS had decided, for example, that covered entities violate Section 1557 if they “deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual.” *Id.* at 31,472 (codified at 45 C.F.R. § 92.207(b)(5)).

ii. The 2016 Rule defined covered entity to include “(1) [a]n entity that operates a health program or activity, any part of which receives Federal financial assistance; (2) [a]n entity established under Title I of the ACA that administers a health program or activity; and (3) [HHS].” *Id.* at 31,466 (codified at 45 C.F.R. § 92.4).

iii. Even though Section 1557 incorporates Title IX, HHS declined “to incorporate Title IX’s blanket religious exemption into [the 2016 Rule].” *Id.* at 31,380. The 2016 Rule provided that “[i]nsofar as the application of any requirement under this part would violate applicable Federal [and] statutory protections for religious freedom and conscience, such application shall not be required.” *Id.* at 31,466 (codified at 45 C.F.R. § 92.2(b)).

B. Development of the Challenged Rule

In December 2016, the United States District Court for the Northern District of Texas preliminarily enjoined enforcement of parts of the 2016 Rule on a nationwide basis, *Franciscan Alliance Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016), *subsequent determination*, 414 F. Supp. 3d 928 (N.D. Tex. 2019). In May 2017, HHS moved to voluntarily remand that rule so that HHS could “assess the reasonableness, necessity, and efficacy” of the rule, *Franciscan Alliance Inc. v. Price*, No. 7:16-cv-00108, at 1, ECF No. 92 (N.D. Tex. May 2, 2017), and in October 2019, the court vacated the rule’s definition of “on the basis of sex” insofar as the definition included “gender identity” and “termination of pregnancy,” *Franciscan Alliance Inc. v. Azar*, 414 F. Supp. 3d 928, 947 (N.D. Tex. 2019), *appeal filed*, No. 20-10093 (5th Cir. Jan. 24, 2020); *Franciscan Alliance Inc. v. Azar*, No. 7:16-cv-00108, ECF No. 182 (N.D. Tex. Nov. 21,

2019). In June 2019, HHS published a Proposed Rule, which sought “to make substantial revisions to the Section 1557 Regulation and to eliminate provisions that are inconsistent or redundant with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability.” Nondiscrimination in Health & Health Education Programs or Activities, 84 Fed. Reg. 27,846, 27,848-49 (June 14, 2019). In so doing, the agency also proposed retaining significant aspects of the 2016 Rule. *Id.* at 27,849. The Proposed Rule would “empower [HHS] to continue its robust enforcement of civil rights laws prohibiting discrimination on the basis of race, color, national origin, sex, age, or disability in [HHS]-funded health programs or activities, and would make it clear that such civil rights laws remain in full force and effect.” *Id.*

C. The 2020 Rule

HHS received nearly 200,000 comments on the Proposed Rule. After carefully evaluating the extensive record, HHS published the Final Rule on June 19, 2020. Nondiscrimination in Health & Health Education Programs or Activities, Delegation of Authority, 85 Fed Reg. 37,160, 37,160 (June 19, 2020). Consistent with the Proposed Rule, the Final Rule makes several revisions to the Section 1557 regulations, ensuring a robust protection of civil rights:

i. Rather than adopt new definitions for existing civil rights statutes, the 2020 Rule follows the approach of Section 1557 itself by simply incorporating those underlying statutes and HHS’s implementing regulations in large part. It thus “repeals the 2016 Rule’s definition of ‘on the basis of sex,’ [and] declines to replace it with a new regulatory definition.” *Id.* at 37,178. It also eliminates the gender identity provision from the 2016 Rule, acknowledging that the decision in *Franciscan Alliance* foreclosed its inclusion. *See, e.g., id.* at 37,164–65. HHS further explained, in the rule’s preamble but not the regulatory text, that, while “the 2016 Rule required covered entities to ‘treat individuals consistent with their gender identity’ in virtually every respect,” *id.* at 37,189, “certain single-sex medical procedures, treatments, or specializations are rooted” in a patient’s biological sex, *id.* at 37,187, and “reasonable distinctions on the basis of

sex” may sometimes be permissible “in the field of health services,” *id.* at 37,185. Accordingly, HHS repealed “a mandate that was, at least, ambiguous and confusing.” *Id.* at 37,187.

HHS made clear, however, that regardless of its views, the inclusion of “gender identity” in the definition of “on the basis of sex” had already been vacated from the 2016 Rule, and that the Final Rule did nothing more than ensure that the Section 1557 regulations “conform to the plain meaning of the underlying civil rights statutes.” *Id.* at 37,161. Because the 2020 Rule merely replaces the 2016 Rule’s explicit definition of “on the basis of sex” by hewing to the text of Section 1557 (and thus Title IX), “to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court’s construction.” *Id.* at 37,168.

ii. The 2020 Rule “modifies the 2016 Rule’s definition of entities covered by Section 1557,” *id.* at 37,162, which will now extend to “(1) any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by [HHS]; (2) any program or activity administered by [HHS] under Title I of the ACA; or (3) any program or activity administered by any entity established under [such Title].” *Id.* at 37,169, 37,244 (codified at 45 C.F.R. § 92.3(a)). HHS changed this definition “in order to align it more closely with the statutory text.” *Id.* at 37,162; *see also id.* at 37,169–71.

iii. The Final Rule incorporates Title IX’s religious exemption, and its abortion neutrality language, because by incorporating Title IX into Section 1557, “Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions” of Title IX. *Id.* at 37,193 (quoting *Franciscan Alliance*, 227 F. Supp. 3d at 690–91); *see also id.* at 37,207–08.

ARGUMENT

I. PLAINTIFFS LACK STANDING

Because “[s]tanding is not dispensed in gross,” *Davis v. FEC*, 554 U.S. 724, 734 (2008) (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996)), plaintiff “must demonstrate standing for

each claim [it] seeks to press” and for “each form of relief sought,” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). Plaintiff, which fails to identify any “injury in fact” that is “fairly . . . trac[able]” to the 2020 Rule and that will be “redressed by a favorable decision,” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 38, 41–42 (1976)), lacks standing to advance any of its claims.

A. Plaintiff Does Not Have *Parens Patriae* Standing.

Plaintiff alleges that it “brings this action to redress harms to its . . . interests as *parens patriae* in protecting the health and well-being of its residents.” Compl. ¶ 9; *see id.* ¶¶ 66–109. But plaintiff, “like all states, ‘does not have standing as *parens patriae* to bring an action against the Federal Government.’” *Sierra Forest Legacy v. Sherman*, 646 F.3d 1161, 1178 (9th Cir. 2011) (citation omitted). Accordingly, alleged injuries to Washington residents may not form the basis of plaintiff’s standing.

B. Plaintiff Fails to Show It is Likely to Suffer a Concrete Injury in Fact.

While plaintiff complains that the 2020 Rule fails to endorse its preferred definition of “on the basis of sex,” fails to prohibit categorical coverage exclusions, restricts what entities are covered by the Rule, and includes various religious exemptions, *see* Mot. for Prelim. Inj., at 8–20, ECF No. 4 (“Mot.”), plaintiff cannot show that it is likely to suffer concrete harm as a result. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016); *Lujan*, 504 U.S. at 560–61. As an initial matter, plaintiff speculates that the 2020 Rule will cause many providers to refuse to provide care based on a religious or conscience objections, Compl. ¶¶ 112, 115, 117, 123–24, or based on discrimination the 2020 Rule purportedly authorizes, *id.* ¶ 118. It then alleges that such third-party actions will lead the State to take on the tasks of “referr[ing]” individuals “to other healthcare providers,” *id.* ¶ 112, or analyzing the impacts of the Rule, *id.* ¶ 113; *see also id.* ¶¶ 125–26 (alleging administrative costs). Plaintiff contends that these responsibilities are “not optional” because otherwise it may be forced to “pay for increased subsidized services for

1 affected individuals later.” *Id.* ¶ 114; *see id.* ¶ 115. It also alleges a loss of tax revenue from lost
 2 healthcare services, *id.* ¶ 119, and job losses, *id.* ¶¶ 120–22.

3 These injuries are wholly conjectural, and a mere threat of potential future harm is
 4 insufficient to establish standing. Plaintiff comes nowhere close to identifying an injury that is
 5 “certainly impending.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 401 (2013) (quoting
 6 *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). Instead, plaintiff’s attenuated causal chain
 7 leading to purported injury relies upon fear of actions third parties *may* take as a result of the
 8 Rule. But it is far from inevitable that any of the alleged discrimination purportedly leading to
 9 these impacts will occur at all. It is no wonder, then, that plaintiff cannot identify which
 10 providers are likely to engage in such conduct, or which residents may be harmed as a result. The
 11 injury alleged is wholly speculative. *See Lujan*, 504 U.S. at 560.

12 Plaintiff’s failure to establish concrete harm is exacerbated by the effect of its own laws.
 13 Washington law, *which the 2020 Rule does not preempt*, already prohibits discrimination on the
 14 basis of gender identity. In particular, Washington’s Law Against Discrimination, Ch. 49.60
 15 RCW, prohibits discrimination based upon sexual orientation, which includes “gender expression
 16 or identity,” defined as “having or being perceived [to have] a gender identity, self-image,
 17 appearance, behavior, or expression, whether or not that gender identity, self-image, appearance,
 18 behavior, or expression is different from that traditionally associated with the sex assigned to that
 19 person at birth.” RCW 49.60.040(26). And Washington state law expressly prohibits entities
 20 “engaged in the business of insurance” from discrimination based on “sex, marital status, or
 21 sexual orientation as defined in RCW 49.60.040, or the presence of any [disability] of the insured
 22 or the prospective insured.” RCW 48.30.300. This prohibition applies in the issuance,
 23 cancellation, or renewal of any contract of insurance, as well as amount of benefits payable, or
 24 any term, rate, condition or type of coverage offered. *Id.* Indeed, *specifically in response to the*
 25 *2020 Rule*, Washington State has clarified that its protections against discrimination continue to
 26 protect a substantial majority of Washingtonians. *See Letter from Mike Kreidler, State of*
 27
 28

1 Washington Insurance Commissioner, to Health Insurance Carriers in Washington State (June
2 23, 2020), [https://www.insurance.wa.gov/sites/default/files/documents/final-letter-health-](https://www.insurance.wa.gov/sites/default/files/documents/final-letter-health-carriers-transgender-protection-non-discrimination.pdf)
3 [carriers-transgender-protection-non-discrimination.pdf](https://www.insurance.wa.gov/sites/default/files/documents/final-letter-health-carriers-transgender-protection-non-discrimination.pdf). Washington law would seem to prevent
4 the very hypothetical injuries complained of within the State.

5 And in any event, the States’ asserted harms are little more than *parens patrie* interests in
6 disguise. To be sure, “an increase in the payment of government benefits, like a decrease in tax
7 revenues, ‘embodies a comprehensible harm to the economic interests of the [State’s]
8 government[.]’” *Commonwealth v. U.S. Dep’t of Educ.*, 340 F. Supp. 3d 7, 17 (D.D.C. 2018)
9 (quoting *Pennsylvania v. Kleppe*, 553 F.2d 668, 676 (D.C. Cir. 1976)). But the State has alleged
10 “no facts about the particular government programs that may [be] impacted, the size of such
11 impact, or the portion of such impact attributable to the” 2020 Rule. *Id.* Its claim is accordingly
12 “the sort of generalized grievance about the conduct of government, so distantly related to the
13 wrong for which relief is sought, as not to be cognizable for purposes of standing.” *Id.* (quoting
14 *Kleppe*, 553 F.2d at 672).
15

16 **C. Plaintiff Cannot Show that the Federal Government Caused its Alleged Injuries**
17 **or that a Decision by this Court will Redress Them.**

18 Even if plaintiff could bring an action against the federal government on behalf of its
19 residents or based on costs stemming from such harm, the alleged injuries to its residents are not
20 caused by defendants or redressable by this Court. Plaintiff cannot show that the defendant’s
21 conduct—rather than that of a third party—caused its injuries, and that a decision in plaintiff’s
22 favor will redress those injuries. *See Lujan*, 504 U.S. at 560.

23 *First*, plaintiff cannot show that any remedy this Court orders is likely to redress the harm
24 complained of. *See Lujan*, 504 U.S. at 561; *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26,
25 41–42 (1976). “To establish Article III redressability, [a] plaintiff[] must show that the relief [it]
26 seek[s] is both (1) substantially likely to redress [its] injuries; and (2) within the district court’s
27 power to award.” *Juliana v. United States*, 947 F.3d 1159, 1170 (9th Cir. 2020). Plaintiff argues
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1 that HHS should have included additional language in the 2020 Rule that might dissuade
 2 healthcare providers from discriminating against the individual Washington residents plaintiff
 3 purports to represent, *see* Compl. ¶¶ 66–101, (and thereby avoid impacts on the State itself, *see*
 4 Compl. ¶¶ 110–27), but there is no available remedy for achieving that end because the gender
 5 identity provision was vacated from the 2016 Rule before the 2020 Rule was finalized, and the
 6 2016 Rule itself omitted sexual orientation as a prohibited discrimination category. Enjoining the
 7 challenged 2020 Rule would thus leave plaintiff with only the non-vacated portions of the 2016
 8 Rule and Section 1557 itself, neither of which contains the definition of sex plaintiff prefers.

9 *Second*, plaintiff cannot demonstrate that the 2020 Rule will cause its alleged injuries. To
 10 establish standing, “there must be a causal connection between the injury and the conduct
 11 complained of—the injury has to be ‘fairly . . . trac[able] to the challenged action of the
 12 defendant, and not . . . th[e] result [of] the independent action of some third party not before the
 13 court.’” *Lujan*, 504 U.S. at 560 (quoting *Simon*, 426 U.S. at 41–42). In *Simon v. Eastern*
 14 *Kentucky Welfare Rights Organization*, for example, the Supreme Court held that plaintiffs
 15 lacked standing to challenge an IRS regulation they believed would induce hospitals to deny
 16 services because “injury at the hands of a hospital is insufficient by itself to establish a case or
 17 controversy . . . [where] no hospital is a defendant.” *See* 426 U.S. at 41.

18 Just like in *Simon*, plaintiff does not allege that the government will injure it by refusing
 19 to provide it with medical services. Instead, plaintiff claims that the various components of the
 20 2020 Rule may lead healthcare providers to deny services to certain patients. *See, e.g.*, Compl.
 21 ¶ 67 (“The Final Rule will . . . invit[e] discrimination against LGBTQ and LEP individuals when
 22 they seek healthcare or insurance.”). To the extent this Rule could be said not to prohibit
 23 behavior plaintiff fears, its dispute would be with healthcare providers who engage in those
 24 practices—not the federal government. *See Linda R.S. v. Richard D.*, 410 U.S. 614, 618 (1973).

25 *Third*, even if this Court could order the agency to rewrite the 2020 Rule according to
 26 plaintiff’s specifications, such a result would not redress plaintiff’s alleged harm. In *Simon*,
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1 plaintiffs attempted to make the very same argument that plaintiff makes here—that a particular
 2 federal policy might encourage individuals to engage in allegedly objectionable conduct.
 3 *Compare Simon*, 426 U.S. at 42 (“The complaint here alleged only that petitioners, by the
 4 adoption of Revenue Ruling 69-545, had ‘encouraged’ hospitals to deny services to indigents.”),
 5 *with* Compl. ¶ 159 (“HHS invites healthcare providers and insurers to interfere with a patient’s
 6 access to medical care.”). As in *Simon*, a favorable judgment here would not prevent third-party
 7 providers from engaging in the conduct plaintiff dislikes. Indeed, to the extent that such
 8 providers plan to engage in such conduct in violation of Washington law, it seems difficult to
 9 understand why this Rule would prevent it. Moreover, it is possible that some providers could
 10 choose to avoid Section 1557 altogether by refusing to accept federal funds. *See* 42 U.S.C.
 11 § 18116(a) (applying restrictions to “any health program or activity, any part of which is
 12 receiving Federal financial assistance”). While forgoing federal funds may not be an attractive
 13 option to many, doing so would be far from unprecedented—in other contexts organizations have
 14 chosen to do precisely that so as to avoid federal regulation.¹

16 *Fourth*, the injuries alleged are primarily predicated on past events. For example, after
 17 alleging that the co-founder of the Gender Justice League, Elayne White, has “heard numerous
 18 stories of discrimination in the healthcare setting against Washington’s transgender and
 19 nonconforming individuals,” Compl. ¶ 88, and recounting some of those stories, *id.* ¶¶ 88–90,
 20 plaintiff alleges that “Elayne Wylie believes that if the Final Rule takes effect, experiences like
 21 the ones described above will increase significantly,” *id.* ¶ 92. But “[p]ast exposure to illegal
 22 conduct does not in itself show a present case or controversy regarding injunctive relief . . . if
 23 unaccompanied by any continuing, present adverse effects.” *City of Los Angeles v. Lyons*, 461
 24 U.S. 95, 102 (1983) (citation omitted). These unidentified third parties’ alleged past harms were
 25 not caused by the 2020 Rule, which has yet to take effect. Plaintiff cannot explain why those past
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27 ¹ For example, Hillsdale College, “[t]o maintain [its] institutional independence, . . . accept[s] no state or federal
 28 funding—even indirectly in the form of student grants or loans.” Hillsdale College, “Scholarships & Financial Aid”
<https://www.hillsdale.edu/admissions-aid/financial-aid/>.

1 harms are now imminent, let alone how the 2020 Rule will cause them. Simply put, speculation
 2 that a yet-to-be-identified private provider may deny service to a yet-to-be identified patient at
 3 some point in the future is insufficient to establish standing vis-à-vis the federal government.
 4 Because “[e]ach of the inferential steps to show causation and redressability depends on
 5 premises as to which there remains considerable doubt,” *Ariz. Christian Sch. Tuition Org. v.*
 6 *Winn*, 563 U.S. 125, 138 (2011), there is no standing to support plaintiff’s challenge.

7 **II. PLAINTIFF HAS NOT DEMONSTRATED A LIKELIHOOD OF SUCCESS ON THE MERITS OF**
 8 **ITS CLAIM THAT THE 2020 RULE VIOLATES THE APA**

9 To obtain a preliminary injunction, a plaintiff “must establish ‘[(1)] that he is likely to
 10 succeed on the merits, [(2)] that he is likely to suffer irreparable harm in the absence of
 11 preliminary relief, [(3)] that the balance of equities tips in his favor, and [(4)] that an injunction
 12 is in the public interest.” *Edge v. City of Everett*, 929 F.3d 657, 663 (9th Cir. 2019) (quoting
 13 *Coffman v. Queen of Valley Med. Ctr.*, 895 F.3d 717, 725 (9th Cir. 2018)). “Likelihood of
 14 success on the merits is the most important factor; if a movant fails to meet this threshold
 15 inquiry, [courts] need not consider the other factors.” *Id.* (quoting *California v. Azar*, 911 F.3d
 16 558, 575 (9th Cir. 2018)). Here, Plaintiff must demonstrate that the 2020 Rule is in excess of
 17 statutory authority or “arbitrary, capricious, an abuse of discretion, or otherwise not in
 18 accordance with law.” 5 U.S.C. §§ 706(2)(A); 706(2)(C). “Review under the arbitrary and
 19 capricious standard is narrow, and [courts do] not substitute [their] judgment for that of the
 20 agency.” *Or. Nat. Desert Ass’n v. U.S. Forest Serv.*, 957 F.3d 1024, 1032 (9th Cir. 2020)
 21 (quoting *The Lands Council v. McNair*, 537 F.3d 981, 987 (9th Cir. 2008)). Plaintiff comes
 22 nowhere close to satisfying this “highly deferential standard”—or establishing any other
 23 violation of the APA. *League of Wilderness Defenders Blue Mountains Biodiversity Project v.*
 24 *Allen*, 615 F.3d 1122, 1130 (9th Cir. 2010).

A. HHS’s Decision Not to Define “On the Basis of Sex” Is Lawful.

The 2020 Rule contains a straightforward application of Title IX’s prohibition against discriminating “on the basis of sex.” 20 U.S.C. § 1681. Plaintiff’s argument that the Rule somehow runs afoul of Section 1557 is meritless.

Plaintiff does not explain *how* the 2020 Rule’s adherence to Title IX’s prohibition of discrimination “on the basis of sex” runs afoul of Section 1557. Section 1557 does not use the term “sex” but instead incorporates the prohibition contained in Title IX, which in turn provides: “No person in the United States shall, on the basis of sex, . . . be subjected to discrimination under any education program or activity receiving Federal financial assistance” *Id.* § 1681(a). By declining to include a definition of “on the basis of sex” in the 2020 Rule, the Rule “relies upon, the plain meaning of the term in the statute.” 85 Fed. Reg. at 37,178. What plaintiff advocates for is the inclusion of language *beyond* what is in the text of Section 1557 and Title IX. Indeed, plaintiff seeks more than even the 2016 Rule provided, which declined to include “sexual orientation” in its definition of “on the basis of sex.” *See* 81 Fed. Reg. at 31,390. Plaintiff provides no legal justification to support such a demand. Section 1557 certainly does not require it. Indeed, Section 1557 did not require HHS to issue any rule at all. *See* 42 U.S.C. § 18116(c). Simply put, although plaintiff complains that the 2020 Rule does not include its preferred language, it provides no argument that HHS was *required* to include a definition of “on the basis of sex,” let alone one that includes “gender identity” or “sexual orientation.”

Plaintiff relies on a series of cases, which it argues stand for the proposition that “on the basis of sex” as used in Section 1557, necessarily includes “gender identity,” “sex stereotyping,” and “sexual orientation.” Mot. at 8–10. Plaintiff presumably does not argue that Title IX itself is impermissible even though, like the 2020 Rule, the text of Title IX does not include the term “gender identity.” *See* 20 U.S.C. § 1681(a). Nor does the text of Title VII, for that matter, which was the statute at issue in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020)—a case upon which plaintiff heavily relies. Mot at 9.

1 Because plaintiff cannot identify anything impermissible in the operative text of the 2020
 2 Rule relating to “on the basis of sex,” it instead takes issue with language in the Rule’s preamble.
 3 For example, plaintiff claims that “HHS’s lengthy discussion of whether the public meaning of
 4 ‘sex’ refers exclusively to the biological binary of male and female is both irrelevant and
 5 misplaced.” Mot. at 10. But this Court’s focus must remain on the text of the Rule itself, as a
 6 “regulatory preamble . . . is not legally binding.” *Peabody Coal Co. v. Director, Office of*
 7 *Workers’ Compensation Programs*, 746 F.3d 1119, 1125 (9th Cir. 2014); *see St. Francis Med.*
 8 *Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018) (a regulation’s preamble “lacks the force and
 9 effect of law”); *see also Wyeth v. Levine*, 555 U.S. 555, 575–77 (2009); *Boose v. Tri-Cty. Metro.*
 10 *Trasp. Dist. of Or.*, 587 F.3d 998, 1005 (9th Cir. 2009). And, in any event, the Rule’s preamble
 11 confirms that, “to the extent that a Supreme Court decision is applicable in interpreting the
 12 meaning of a statutory term, the elimination of a regulatory definition of such term would not
 13 preclude application of the Court’s construction.” 85 Fed. Reg. at 37,168. Plaintiff fails to
 14 explain how HHS’s decision to rely on the statutory text, rather than adopt its own statutory
 15 definition that could be affected by changing case law, is impermissible.

17 Plaintiff relatedly argues the 2020 Rule should include a provision explicitly barring
 18 covered entities from prohibiting certain gender-transition procedures and services, *see* Mot. at
 19 11, even though Section 1557 does not require such a provision. As an initial matter, plaintiff
 20 mischaracterizes the 2020 Rule as “grant[ing] permission for insurance plans to categorically
 21 exclude gender-transition care from coverage.” *Id.* at 11. Nowhere does the 2020 Rule provide
 22 such “authorization.” Although HHS’s 2016 Rule prohibited covered entities from “[h]av[ing] or
 23 implement[ing] a categorical coverage exclusion or limitation for all health services related to
 24 gender transition,” 45 C.F.R. § 92.207(b)(4), Section 1557 did not require that mandate.
 25 Eliminating the mandate to cover such procedures does not constitute an authorization of any
 26 particular conduct. To the extent that such conduct is covered by Section 1557, it is also covered
 27 by the 2020 Rule. HHS’s determination to remove the explicit categorical prohibition was, at the
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1 very least, a reasonable one entitled to deference. *See Chevron, U.S.A., Inc. v. Nat. Res. Def.*
2 *Council, Inc.*, 467 U.S. 837, 844 (1984). Indeed, even the 2016 Rule recognized that “[t]he
3 enumeration of specific forms of discrimination . . . does not limit the general applicability of the
4 prohibition” against covered discrimination. 81 Fed. Reg. at 31,472 (codified at 45 C.F.R.
5 § 92.207(c)). The 2020 Rule similarly defers to the statutory text.

6 Plaintiff argues, in the alternative, that even if the 2020 Rule is otherwise lawful, HHS’s
7 reasoning in support was arbitrary and capricious, 5 U.S.C. § 706(2)(A). *See* Mot. at 15–19.
8 Because the 2020 Rule “remain[s] within the bounds of reasoned decisionmaking,” *California v.*
9 *Azar*, 950 F.3d 1067, 1097 (9th Cir. 2020) (quoting *Dep’t of Commerce v. New York*, 139 S. Ct.
10 2551, 2569 (2019)), it does not violate the APA.

11 Plaintiff first criticizes HHS for relying, in part, on *Franciscan Alliance* as justification
12 for not including a definition for “on the basis of sex,” *see* Mot. at 16, but that decision vacated
13 the language for which plaintiff now advocates. *See* 414 F. Supp. 3d at 947. It was entirely
14 reasonable for HHS to justify not including an expanded definition of “on the basis of sex” when
15 that portion of the 2016 Rule was no longer legally enforceable; indeed, *Franciscan Alliance*
16 compelled HHS to follow such a course. As HHS explained, “[t]his final ruling is binding,” and
17 as a result, “the Department’s Section 1557 regulation, as currently operative, does not contain
18 the 2016 Rule’s definition of ‘on the basis of sex’ to encompass gender identity and termination
19 of pregnancy.” 85 Fed. Reg. at 37,168. *Franciscan Alliance*’s vacatur of plaintiff’s desired
20 definition of “on the basis of sex” was therefore reason enough for HHS not to include it in the
21 2020 Rule. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513–16 (2009).

22 Plaintiff argues that it was arbitrary and capricious for HHS to move forward with the
23 Rule knowing that a decision from the Supreme Court in *Bostock* was imminent. Mot. at 16. But
24 *Bostock* was a case involving a different statute—Title VII—and the Supreme Court expressly
25 limited its reasoning to that statute, leaving its application elsewhere for another day. *See* 140 S.
26 Ct. at 1753. HHS thus acted reasonably in finalizing its rule without waiting additional months or
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1 years for future decisions applying *Bostock* to Title IX. This is especially true in light of the
 2 Rule’s preamble, which makes clear that, “to the extent that a Supreme Court decision is
 3 applicable in interpreting the meaning of a statutory term, the elimination of a regulatory
 4 definition of such term would not preclude application of the Court’s construction.” 85 Fed. Reg.
 5 at 37,168. Because, as HHS recognized, the Rule’s text allows for future judicial interpretation of
 6 the underlying statutes, it was reasonable for HHS to move forward with the 2020 Rule.

7 Plaintiff criticizes HHS’s statement that it “knows of no data showing that the proper
 8 enforcement of Federal nondiscrimination law according to statutory text will disproportionately
 9 burden individuals on the basis of sexual orientation and/or gender identity,” *Id.* at 37,182; *see*
 10 Mot. at 16–17, and asserts that HHS did not account for “the public health impacts of
 11 discrimination,” *see* Mot. at 17. These claims relate to a cost-benefit analysis that is not subject
 12 to judicial review. HHS undertook a cost-benefit analysis to comply with Executive Orders
 13 12866 and 13563, 85 Fed. Reg. at 37,222, and alleged violations of these “Executive Orders
 14 cannot give rise to a cause of action” under the APA. *Fla. Bankers Ass’n v. U.S. Dep’t of*
 15 *Treasury*, 19 F. Supp. 3d 111, 118 n.1 (D.D.C. 2014), *vacated on other grounds*, 799 F.3d 1065
 16 (D.C. Cir. 2015); *see Air Transp. Ass’n v. FAA*, 169 F.3d 1, 8-9 (D.C. Cir. 1999).

18 Even if the cost-benefit analysis was reviewable, it was perfectly reasonable for HHS to
 19 “value[] at zero,” Mot. at 16, any harm stemming from the “changes” from the 2016 Rule to the
 20 2020 Rule with respect to HHS’s decision not to define “on the basis of sex.” Any such
 21 “changes” were nonexistent. As HHS explained in the preamble, “[b]ecause the 2016 Rule
 22 explicitly declined to make sexual orientation a protected category, and because the Rule’s
 23 gender identity provision has been legally inoperative since December 31, 2016, to the extent
 24 that LGBT individuals suffer future harms, it cannot be attributed to the Department’s finalizing
 25 this rule, as opposed to other causes.” 85 Fed. Reg. at 37,182. Such a position was entirely
 26 reasonable.²

27
 28 ² And, as HHS further noted, covered entities will likely implement policies to comply with applicable law, which often includes state antidiscrimination law, *id.* at 37,225. Neither Section 1557 nor the APA requires more.

B. The 2020 Rule’s Religious Exemption Does Not Violate the APA.

HHS’s decision to follow Section 1557’s command and incorporate the full scope of Title IX’s antidiscrimination protection was in accordance with that statute. Section 1557 prohibits discrimination “on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.).” 42 U.S.C. § 18116(a). Section 1557 thereby expressly incorporates the very statutory provision that plaintiff says should not be incorporated, the religious exemption, 20 U.S.C. § 1681(a)(3). And Section 1557 evinces no intent to exclude Title IX’s religious exemption. Plaintiff argues that Section 1557 supposedly “omits” the religious exemption, but Section 1557 “omits” all of the text of Title IX, instead incorporating it by reference. Nor does plaintiff benefit from any presumption regarding the scope of exemptions from civil rights statutes—the question is whether Section 1557 incorporates the religious exemption at all, not how broadly that exemption should be read.³

The plain text of Section 1557 and Title IX support HHS’s decision to include the religious exemption in the 2020 Rule: Section 1557 prohibits discrimination “on the ground prohibited under . . . title IX,” 42 U.S.C. § 18116(a), and, for an “educational institution which is controlled by a religious organization,” making a decision on the basis of sex is not a ground prohibited under § 1681(a)(3) if applying the restriction “would not be consistent with the religious tenets of such organization.” 20 U.S.C. § 1681(a)(3). That is the same conclusion reached by the court in *Franciscan Alliance* when it vacated the 2016 Rule in part for failing to incorporate Title IX’s religious exemption. *Franciscan Alliance*, 227 F. Supp. 3d at 690–91 (“[A] religious organization refusing to act inconsistent with its religious tenets on the basis of sex does not discriminate on the ground prohibited by Title IX.”). And regardless of whether Section 1557 unambiguously requires the incorporation of Title IX’s religious exemption, that construction of the statute is at least a reasonable. *See Chevron*, 467 U.S. at 844.

³ Nor is Section 1554 implicated; “§ 1554 is meant to prevent direct government interference with health care,” *California*, 950 F.3d at 1094, and plaintiff has identified no way in which Title IX’s religious exemption is a direct government interference with health care.

1 Plaintiff likewise cannot succeed in its claim that HHS failed to provide a good reason for
2 its decision to incorporate Title IX's religious exemption. HHS acknowledged that it was
3 changing positions and proffered "good reasons" for its new policy, which is all that the APA
4 requires. *Fox*, 556 U.S. at 515. Specifically, HHS explained that its previous exclusion of the
5 exemption was not based on the best reading of Title IX, that the lack of an exclusion had made
6 the rule vulnerable to legal attack (and had already led to an injunction), and that expressly
7 incorporating the religious exemption would better protect the rights of religious objectors.

8 Furthermore, "an agency may justify its policy choice by explaining why that policy 'is
9 more consistent with statutory language' than alternative policies." *Encino Motorcars, LLC v.*
10 *Navarro*, 136 S. Ct. 2117, 2127 (2016) (quoting *Long Island Care at Home, Ltd. v. Coke*, 551
11 U.S. 158, 175 (2007)). The 2016 Rule took the position that Title IX's religious exemption was
12 "limited in scope to educational institutions." 81 Fed. Reg. at 31,380. But in promulgating the
13 2020 Rule, HHS explained why it disagreed with that previous conclusion. 85 Fed. Reg. at
14 37,207. By its own terms, Title IX applies to "any education program or activity receiving
15 Federal financial assistance," 20 U.S.C. § 1681(a), and Title IX has long been understood to
16 apply outside of core educational institutions. Indeed, Title IX defines a "program or activity"
17 under § 1681(a) to include "all of the operations" of "an entire corporation, partnership, or other
18 private organization" that "is principally engaged in the business of providing education, *health*
19 *care*, housing, social services, or parks and recreation." *Id.* § 1687(3)(A)(ii) (emphasis added).
20 That provision shows that Title IX's presence in healthcare settings was expressly anticipated,
21 and the history of Title IX's application shows the same. *See Doe v. Mercy Catholic Med. Ctr.*,
22 850 F.3d 545, 558 (3d Cir. 2017). In sum, HHS determined in its sound judgment that its
23 previous interpretation had been incorrect.
24

25 Another good reason HHS offered was that the exclusion of religious exemptions had
26 caused the 2016 Rule to be vacated in part in *Franciscan Alliance*. 85 Fed. Reg. at 37,207. The
27 Supreme Court has recognized that agencies may legitimately consider past court decisions
28

1 regarding the need for religious exemptions when crafting regulations. When the Supreme Court
 2 recently upheld the conscience exemptions to the contraceptive mandate, the Court noted that its
 3 own past decisions “all but instructed the Departments to consider [the Religious Freedom
 4 Restoration Act (RFRA)] going forward.” *Little Sisters of the Poor Saints Peter & Paul Home v.*
 5 *Pennsylvania*, 140 S. Ct. 2367, 2383 (2020). It was, the Court held, “hard to see how the
 6 Departments could promulgate rules consistent with these decisions if they did not overtly
 7 consider these entities’ rights under RFRA.” *Id.* Indeed, the Court opined that failing to consider
 8 the Court’s instruction would make the regulation “susceptible to claims that the rules were
 9 arbitrary and capricious for failing to consider an important aspect of the problem.” *Id.* at 2384.
 10 The same is true here—the 2016 Rule had been vacated in part for failing to provide religious
 11 exemptions, and it was reasonable for HHS to take that into account in including Title IX’s
 12 religious exemption in the new rule.

13
 14 Yet another good reason offered for the rule was the desire to “protect . . . providers’
 15 medical judgment and their consciences,” 85 Fed. Reg. at 37,206, which is widely recognized as
 16 a legitimate government objective. *See Corp. of the Presiding Bishop of the Church of Jesus*
 17 *Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 338 (1987). And Congress has repeatedly
 18 demonstrated through legislation that accommodation of religion is an important and legitimate
 19 goal of the government—for example, it has passed wide-ranging protections for religious
 20 liberty, such as RFRA and RLUIPA, and has also explicitly created religious exemptions in
 21 many individual statutes, such as Title VII and Title IX.

22 **C. The 2020 Rule Properly Construes the Scope of Section 1557.**

23 Plaintiff takes exception with two aspects of the 2020 Rule’s determination of what
 24 constitutes a “covered entity.” Because both provisions faithfully construe Section 1557, neither
 25 of plaintiff’s arguments has merit.

26
 27 *First*, plaintiff argues that the 2020 Rule impermissibly “limit[s] Section 1557 coverage
 28 to health programs administered by the HHS *under the ACA only*.” Mot. at 14 (emphasis added).

1 As an initial matter, the 2020 Rule is not so limited, but extends to “[a]ny health program or
2 activity, any part of which is receiving Federal financial assistance (including credits, subsidies,
3 or contracts of insurance) provided by [HHS]” as well as programs or activities “administered by
4 [HHS] under the [ACA]” or “administered by any entity established under [the ACA].” 85 Fed.
5 Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(a)).

6 In any event, contrary to plaintiff’s contention, the language HHS selected represents the
7 most reasonable construction of Section 1557, which provides that nondiscrimination protections
8 apply to “any health program or activity, any part of which is receiving Federal financial
9 assistance, . . . [and] any program or activity that is administered by an Executive Agency or any
10 entity established under this title [*sc.*, Title I].” 42 U.S.C. § 18116(a). If the second category
11 were read piecemeal, Section 1557 would apply to “any program or activity that is administered
12 by an Executive Agency”—i.e., *all federal action*, regardless of its connection to healthcare or
13 HHS (as well as to any program or activity that is administered by any entity established under
14 Title I). Clearly, Congress did not intend to have HHS regulate non-healthcare-related
15 discrimination in programs administered by other agencies. If Congress had wanted to subject *all*
16 federal activity to Section 1557’s restrictions, it would have said so clearly rather than burying
17 such an expansive provision within the ACA, which everywhere else deals exclusively with
18 healthcare; it also, presumably, would not have given HHS express authority to adopt
19 implementing regulations if the statute was meant to govern other agencies. *See* 42 U.S.C.
20 § 18116. “Congress . . . does not alter the fundamental details of a regulatory scheme,” let alone
21 the sum total of federal activity, “in vague terms or ancillary provisions—it does not, one might
22 say, hide elephants in mouseholes.” *Whitman v. Am. Trucking Ass’n*, 531 U.S. 457, 468 (2001).
23 Thus, Section 1557 necessarily must be read in context.

24 To avoid an improperly expansive reading of the provision, HHS construed Section 1557
25 to mean “[a]ny health program or activity, any part of which is receiving Federal financial
26 assistance . . . provided by the Department,” “[a]ny program or activity administered *by the*
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1 *Department under Title I of the Patient Protection and Affordable Care Act,”* and “[a]ny
2 program or activity administered by any entity established under such Title.” 85 Fed. Reg. at
3 37,244 (to be codified at 45 C.F.R. § 92.3(a)) (emphasis added). Plaintiff complains that such a
4 construction represents a departure from “the plain language of the statute.” Mot. at 14. But even
5 the 2016 Rule—which plaintiff defends—“acknowledged implicitly what the Department now
6 states more clearly: The grammar of the relevant sentence in the Section 1557 statutory text
7 concerning limits to its scope is less clear than it could have been.” 85 Fed. Reg. at 37,170. To
8 address that ambiguity, the prior rule applied Section 1557 to “every *health* program or activity
9 administered *by the Department*; and every *health* program or activity administered by a Title I
10 entity.” 45 C.F.R. § 92.2(a) (emphasis added). While such a construction avoided applying
11 Section 1557 to *all* federal programs and activities, which plaintiff seemingly agrees would be
12 impermissible, it required injecting the word “health” into the relevant portion of the text, even
13 though Congress had not included the word in the clause. *See* 85 Fed. Reg. at 37,170. In the 2020
14 Rule, HHS instead chose to rely upon the limitation already in the text—that is, Title I programs
15 and activities. *See id.* That approach is, if not the only permissible construction, at least a
16 reasonable construction of the statute that warrants deference. *See Chevron*, 467 U.S. at 844.

17
18 Plaintiff’s argument that the 2020 Rule’s interpretation somehow renders part of the
19 statute superfluous, Mot. at 14, is erroneous. Specifically, plaintiff says that “[i]f ‘under this title’
20 applied to ‘Executive Agency,’ there would have been no need for Section 1557 to reference
21 programs administered by Executive [A]gencies at all.” *Id.* But unlike, for example, the health
22 insurance exchanges established under the ACA, HHS is not an entity established by the ACA.
23 Instead, HHS administers programs or activities under the ACA. So even assuming there is
24 sometimes overlap between a “program or activity administered by” Executive Agencies under
25 “Title I of the Patient Protection and Affordable Care Act,” and a “program or activity
26 administered by any entity established under such Title,” 85 Fed. Reg. at 37,244 (to be codified
27 at 45 C.F.R. § 92.3(a)), the overlap is far from complete.
28

1 *Second*, plaintiff argues that the 2020 Rule’s exclusion of health insurers was
 2 unreasonable. *See* Mot. at 14–15. That argument fails too. As noted above, Section 1557
 3 protections extend, in relevant part, to “any health program or activity” receiving federal
 4 financial assistance. 42 U.S.C. § 18116(a). The 2020 Rule construes the phrase as
 5 “encompass[ing] all of the operations of entities principally engaged in the business of providing
 6 healthcare that receive Federal financial assistance.” 85 Fed. Reg. at 37,244 (to be codified at 45
 7 C.F.R. § 92.3(b)). The Rule goes on to explain that “an entity principally or otherwise engaged in
 8 the business of providing health insurance shall not, by virtue of such provision, be considered to
 9 be principally engaged in the business of providing healthcare.” *Id.* at 37,244–45.⁴

10 Plaintiff takes issue with the fact that “healthcare” is not a term found in Section 1557.
 11 Mot. at 15. But in light of the statute’s silence as to the precise reach of the term “health program
 12 or activity,” HHS reasonably defined it by reference to the definition of that exact term in the
 13 civil rights context. Specifically, HHS noted that the Civil Rights Restoration Act defined
 14 “‘program or activity’ in the underlying statutes to apply to all of an entities’ operations when it
 15 is principally engaged in the business of providing ‘healthcare.’” 85 Fed. Reg. at 37,172. *See*
 16 *Mozilla Corp. v. FCC*, 940 F.3d 1, 25 (D.C. Cir. 2019) (agency interpretation reasonable where
 17 consistent with another regulatory regime interpreting “nearly verbatim” statutory text rationally
 18 related to the statute at issue). Health insurance is, at most, only a health-*related* program or
 19 activity. To be sure, health insurance is an important tool in ensuring patients receive health
 20 services. But just as one would not say that one’s homeowner’s insurance provides a lodging
 21 program or activity, HHS reasonably relied on a preexisting statutory definition of “program or
 22 activity” from the civil rights context instead of concluding that health insurance is a “health
 23 program or activity” within the meaning of Section 1557.
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 28 ⁴ Certain health insurance products would remain subject to Section 1557. For example, a Qualified Health Plan
 “would be covered by the rule because it is a program or activity administered by an entity established under Title I
 (i.e., an Exchange), pursuant to § 92.3(a)(3).” 85 Fed. Reg. at 37,174.

1 Finally, plaintiff argues that in construing Section 1557's scope, HHS "departs from the
 2 2016 Rule without good reason." Mot. at. 19. But "[a]n explanation of why one 'policy is more
 3 consistent with statutory language than alternative policies' is a good reason for a policy
 4 change." *District of Columbia v. U.S. Dep't of Agriculture*, __ F. Supp. 3d. __, 2020 WL
 5 1236657, at *12 (D.D.C. Mar. 13, 2020) (quoting *Encino Motorcars*, 136 S. Ct. at 2127), *filing*
 6 *appeal*, No. 20-5136 (D.C. Cir. May 14, 2020). And that is exactly what HHS did. As explained,
 7 the 2020 Rule provides the most reasonable interpretation of Section 1557's scope in light of the
 8 unchallenged principle that Congress did not intend it "to apply to every program or activity
 9 administered by every Executive agency whether or not it had any relation to health." 84 Fed.
 10 Reg. at 27,862. Far from "casually ignor[ing]" the 2016 Rule's definition of Section 1557's
 11 scope, *see* Mot. at 19 (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C.
 12 Cir. 1970)), or departing from it "sub silentio," *Fox*, 556 U.S. at 515, HHS explained that it
 13 chose to rely upon a limitation already in the statutory language—that is, Title I programs and
 14 activities—instead of injecting the word "health" into the statute. *See* 85 Fed. Reg. at 37,170.

16 **III. PLAINTIFF HAS NOT DEMONSTRATED IRREPARABLE HARM**

17 "[P]laintiffs may not obtain a preliminary injunction unless they can show that irreparable
 18 harm is likely to result in the absence of the injunction." *All. for the Wild Rockies v. Cottrell*, 632
 19 F.3d 1127, 1135 (9th Cir. 2011). To establish a likelihood of irreparable harm, plaintiff "must do
 20 more than merely allege imminent harm sufficient to establish standing; [they] must *demonstrate*
 21 immediate threatened injury." *Boardman v. Pac. Seafood Grp.*, 822 F.3d 1011, 1022 (9th Cir.
 22 2016) (citation omitted). Plaintiff has failed to carry this burden because its alleged injuries are
 23 speculative and it has provided no evidence that such harms will occur immediately.

24 Plaintiff has primarily alleged anticipated effects of the Rule on individual state residents
 25 and suggested the possibility that plaintiff will be harmed through the harm to those individuals,
 26 or as a result of individuals' decisions in response to the Rule. *See* Mot. 20–21. The harm
 27 directly to individuals does not support standing for States under Article III, let alone irreparable
 28

harm. *See Sherman*, 646 F.3d at 1178. In addition, as discussed *supra* I.B, plaintiff’s alleged public health and financial harms are speculative, founded on an attenuated chain of inferences, and contingent on the aggregate decisions of independent third parties to take action not required by the Rule (and prohibited by Washington law). This falls far short of the showing necessary to obtain a preliminary injunction. *See Park Vill. Apt. Tenants Ass’n v. Mortimer Howard Trust*, 636 F.3d 1150, 1160 (9th Cir. 2011) (“a mere ‘possibility of some remote future injury’” is insufficient) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008))); *Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988) (“Speculative injury does not constitute irreparable injury.”). Furthermore, plaintiff cannot show a likelihood of irreparable harm with respect to HHS removing the definition of “on the basis of sex”; the 2020 Rule hews to the statutory text, which is what plaintiff would be left with in light of *Franciscan Alliance* if this Court enjoined this aspect of the Rule.

IV. THE BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR DEFENDANTS

The balance of hardships and the public interest weigh against issuing an injunction here. Where the federal government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). There is inherent harm to an agency in preventing it from implementing regulations that Congress has found to be in the public interest to direct that agency to develop. *See, e.g., City & Cty. of San Francisco v. U.S. Citizenship & Immigration Servs.*, 944 F.3d 773, 806 (9th Cir. 2019) (holding that it would irreparably harm the Department of Homeland Security to prevent it from enforcing a regulation “in a way that comports with its legal authority”).

V. NATIONWIDE RELIEF IS INAPPROPRIATE

Even if the Court were to disagree with defendants’ arguments, any preliminary injunctive relief should be no broader than necessary to provide plaintiff with relief and therefore should extend only to the State of Washington. “A plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury,” *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and “injunctive

relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs,” *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979)). These principles apply with even greater force to a preliminary injunction, an equitable tool designed merely to “preserve the relative positions of the parties until a trial on the merits can be held.” *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). Accordingly, the Ninth Circuit has repeatedly vacated or stayed the nationwide scope of injunctions. *See, e.g., E. Bay Sanctuary Covenant v. Barr*, 934 F.3d 1026, 1029 (9th Cir. 2019) (“all injunctions—even ones involving national policies—must be ‘narrowly tailored to remedy the specific harm shown.’”); *see California v. Azar*, 911 F.3d 558, 584 (9th Cir. 2018) (collecting cases).

Entering broad relief would be particularly inappropriate here because the Rule is being challenged in other courts. *See Whitman-Walker Clinic, Inc. v. HHS*, No. 1:20-cv-1630 (D.D.C.); *Asapansa-Johnson Walker v. Azar*, No. 1:20-cv-2834 (E.D.N.Y.); *BAGLY v. HHS*, No. 1:20-cv-11297 (D. Mass.); *New York v. HHS*, 1:20-cv-5583 (S.D.N.Y.). A nationwide injunction would preclude courts from testing plaintiff’s challenges to the Rule’s operation in other jurisdictions. Moreover, non-plaintiff entities may prefer for the Rule to take effect, affording them certainty regarding the obligations of covered entities in protecting important nondiscrimination rights. For the same reasons, a stay of the effective date pursuant to 5 U.S.C. § 705 is not warranted. *Washington v. U.S. Dep’t of Homeland Sec.*, 408 F. Supp. 3d 1191, 1212 (E.D. Wash. 2019) (preliminary injunctions and § 705 require “application of similar standards”).

In addition, it is important to note that plaintiff has requested that only three provisions of the 2020 Rule be enjoined. If this Court determines that plaintiff’s challenge to one of these provisions is likely to succeed, it should limit any injunction solely to that provision, leaving the remaining provisions intact—especially in light of the fact that provisions of the 2020 Rule are unquestionably severable. *See* 85 Fed. Reg. at 37,245 (codified at 45 C.F.R. § 92.3(d)).

CONCLUSION

Plaintiff’s motion should be denied.

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2 Dated: August 10, 2020

Respectfully submitted,

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